TENT COOPERATION TRE

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 20 September 2000 (20.09.00)	
International application No. PCT/CA99/01147	**Applicant's or agent's file reference** 77813-2
International filing date (day/month/year) 01 December 1999 (01.12.99)	**Priority date** (day/month/year) 01 December 1998 (01.12.98)
Applicant MURDIN, Andrew, D. et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

30 June 2000 (30.06.00)

[] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Manu Berrod
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

CA9901147

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F ENT COOPERATION TREA

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

WHEELER, Michael, E.
Smart & Biggar
900-55 Metcalfe Street
P.O. Box 2999
Station D
Ottawa, Ontario K1P 5Y6
CANADA

Date of mailing (day/month/year)
31 July 2000 (31.07.00)

Applicant's or agent's file reference
77813-2

IMPORTANT NOTIFICATION

International application No.
PCT/CA99/01147

International filing date (day/month/year)
01 December 1999 (01.12.99)

1. The following indications appeared on record concerning:

[X] the applicant [] the inventor [] the agent [] the common representative

Name and Address
CONNAUGHT LABORATORIES LIMITED
1755 Steeles Avenue West
Toronto, Ontario M2R 3T4
Canada

State of Nationality: CA
State of Residence: CA
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[] the person [X] the name [] the address [] the nationality [] the residence

Name and Address
AVENTIS PASTEUR LIMITED
1755 Steeles Avenue West
Toronto, Ontario M2R 3T4
Canada

State of Nationality: CA
State of Residence: CA
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[] the International Searching Authority
[] the International Preliminary Examining Authority
[X] the designated Offices concerned
[] the elected Offices concerned
[] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer
Maria Victoria CORTIELLO

Telephone No.: (41-22) 338.83.38

Form PCT/IB/306 (March 1994) 003438713

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P ENT COOPERATION TREA

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

WHEELER, Michael, E.
Smart & Biggar
900-55 Metcalfe Street
P.O. Box 2999
Station D
Ottawa, Ontario K1P 5Y6
CANADA

Date of mailing (day/month/year)
19 March 2001 (19.03.01)

Applicant's or agent's file reference
77813-2

IMPORTANT NOTIFICATION

International application No.
PCT/CA99/01147

International filing date (day/month/year)
01 December 1999 (01.12.99)

1. The following indications appeared on record concerning:

[X] the applicant [X] the inventor [] the agent [] the common representative

Name and Address	State of Nationality	State of Residence
WANG, Joe 48 29th Street Etobicoke, Ontario M8W 3A8 Canada	CA	CA
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[] the person [] the name [X] the address [] the nationality [] the residence

Name and Address	State of Nationality	State of Residence
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	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[] the International Searching Authority
[X] the International Preliminary Examining Authority
[] the designated Offices concerned
[X] the elected Offices concerned
[] other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Catherine Massetti
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/306 (March 1994)

003905493

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PATENT COOPERATION TREA

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

WHEELER, Michael, E.
Smart & Biggar
900-55 Metcalfe Street
P.O. Box 2999
Station D
Ottawa, Ontario K1P 5Y6
CANADA

Date of mailing (day/month/year)
19 March 2001 (19.03.01)

Applicant's or agent's file reference
77813-2

IMPORTANT NOTIFICATION

International application No.
PCT/CA99/01147

International filing date (day/month/year)
01 December 1999 (01.12.99)

1. The following indications appeared on record concerning:

[X] the applicant [X] the inventor [] the agent [] the common representative

Name and Address
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146 Rhodes Circle
Newmarket, Ontario L3X 1V2
Canada

State of Nationality: CA
State of Residence: CA
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[] the person [] the name [X] the address [] the nationality [] the residence

Name and Address
MURDIN, Andrew, D.
11 Forest Hill Drive
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Canada

State of Nationality: CA
State of Residence: CA
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[] the International Searching Authority
[X] the International Preliminary Examining Authority
[] the designated Offices concerned
[X] the elected Offices concerned
[] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

Authorized officer
Catherine Massetti
Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

WHEELER, Michael E. et al
SMART & BIGGAR
P.O. Box 2999, Station D
900-55 Metcalfe Street
Ottawa, Ontario K1P 5Y6
CANADA

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	22.03.2001
Applicant's or agent's file reference 77813-2	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA99/01147	01/12/1999	01/12/1998

Applicant
CONNAUGHT LABORATORIES LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Emslander, S Tel.+49 89 2399-8718

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
77813-2		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA99/01147	01/12/1999	01/12/1998
International Patent Classification (IPC) or national classification and IPC C12N15/62		
Applicant CONNAUGHT LABORATORIES LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

 ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of 14 sheets.

3. This report contains indications relating to the following items:

 - I ☒ Basis of the report
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
 - VI ☒ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
30/06/2000	22.03.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Ury, A Telephone No. +49 89 2399 8411

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA99/01147

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:
Description, pages:

1-7,9-49	as originally filed			
8,8a	with telefax of	19/12/2000		
61	as received on	08/03/2001	with letter of	06/03/2001

Claims, No.:

1-39	as received on	08/03/2001	with letter of	06/03/2001

Drawings, sheets:

1/77-77/77	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

 These elements were available or furnished to this Authority in the following language: , which is:

 - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 - ☐ the language of publication of the international application (under Rule 48.3(b)).
 - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 - ☐ contained in the international application in written form.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority in written form.
 - ☐ furnished subsequently to this Authority in computer readable form.
 - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

 ☐ the description, pages:
 ☐ the claims, Nos.:
 ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

 (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)
 see separate sheet

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

 ☐ the entire international application.

 ☒ claims Nos. 1-30 (all partially).

because:

 ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

 ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

 ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

 ☒ no international search report has been established for the said claims Nos. 1-30 (all partially).

2. A meaningful international preliminary examination report cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

 ☐ the written form has not been furnished or does not comply with the standard.
 ☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;

citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-14, 17-30
	No:	Claims	15, 16
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-30
Industrial applicability (IA)	Yes:	Claims	1-26, 28, 29
	No:	Claims	

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Item I.

The amendments filed with the letter dated 06.03.01 introduce subject-matter which extend beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. A great number of amendments have been introduced in the new set of claims filed with the letter of 06.03.01. Said amendments have not been clearly identified (lack of clear indication with respect to the application as originally filed).
Without such clear indications the IPEA is not prepared to make a detailed examination of said claims with regard to compliance with Article 34(2)(b) PCT. However, at first sight the following defects have been identified:
- The phrase "modified to improve its immunogenicity" has been replaced by the phrase "without loss of immunogenicity" throughout the claims. The first phrase implies an increase in immunogenicity whereas the second one does not imply such an increase. The scope of many claims has therefore been extended.
- The formulation "...N.A. is expressed as a polypeptide..." (originally filed claim 8) has been replaced by the expression "... N.A. is capable of being expressed..." (last part of amended claims 8 and 9). This introduces new subject-matter which extends beyond the content of the application as filed since the expression of N.A. is not limited to polypeptides (includes also, e.g. mRNA).

No basis for these amendments can be found in the application as filed.

Consequently, this report has been established as if said amendments had not been made (Rule 70.2(c) PCT), i.e. **has been established on the basis of claims 1-30 as originally filed.**

Item V.

1) Document D2 ("Database EMBL, accession number 086164, 01.11.98, Knudsen et al.") discloses an amino acid sequence which is identical to that of SEQ ID NO:11. D2 is thereby novelty destroying for claims 15 and 16 (Article 33.2 PCT).

In order to solve the underlying problem (page 8, lines 13-15 of the description)

the skilled person would have started from the protein of D2 identified as an outer membrane complex (OMC) protein of *C. pneumoniae.*
Given that the determination of the corresponding N.A. sequence does not appear to go beyond the knowledge and capabilities of the skilled person, claims 1 and 2 lack an inventive step. The features recited in claims 3-14 and 17-30 are either purely conventional or relate to obvious alternatives which do not appear to require any inventive skill (Article 33.3 PCT).

2) For the assessment of the present claims 27 and 30 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Item VI.

Certain published documents (Rule 70.10)

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO 98/58953	30.12.98	19.06.98	23.06.97
WO 99/27105	03.06.99	20.11.98	21.11.97 04.11.98

Item VIII.

Claims 13 and 14 are unclear (Article 6 PCT) because the "stringent hybridization conditions" mentioned in the claims are not precisely defined **therein**.

species-specific 54-kilodalton protein of Chlamydia pneumoniae. Clin Diagn Lab Immunol. 1997 Nov; 4(6): 700-704). A publication relevant to 98 KDa proteins is Perez Melgosa et al. FEMS Microbiology Letters. 112(2): 199-204. 1993. Another relevant publication is Knudsen, Database EMBL, accession number 086164, 01-11-1998.

Immunoblotting of isolates with sera from patients does show variation of blotting patterns between isolates, indicating that serotypes *C. pneumoniae* may exist (Grayston et al. (1995) Journal of Infectious Diseases 168:1231; Ramirez et al (1996) Annals of Internal Medicine 125:979). However, the results are potentially confouned by the infection status of the patients, since immunoblot profiles of a patient's sera change with time post-infection. An assessment of the number and relative frequency of any serotypes, and the defining antigens, is not yet possible.

Accordingly, a need exists for identifying and isolating polynucleotide sequences of *C. pneumoniae* for use in preventing and treating Chlamydia infection.

SUMMARY OF THE INVENTION

The present invention provides purified and isolated polynucleotide molecules that encode *Chlamydia* polypeptides which can be used in methods to prevent, treat, and diagnose *Chlamydia* infection. In one form of the invention, the polynucleotide molecules are selected from DNA that encode polypeptides CPN100634 (SEQ ID. Nos: 1 and 2), CPN100635 (SEQ ID Nos: 3 and 4), CPN100638 (SEQ ID Nos: 5 and 6), CPN100639 (SEQ ID Nos: 7 and 8), and CPN100708 (SEQ ID Nos: 9 and 10).

Another form of the invention provides polypeptides corresponding to the isolated DNA molecules. The amino acid sequences of the corresponding encoded polypeptides are shown for CPN100634 as SEQ ID No: 11, CPN100635 as SEQ ID Nos: 12 and 13, CPN100638 as SEQ ID No: 14, CPN100639 as SEQ ID No: 15, and CPN 100708 as SEQ ID No: 16.

Those skilled in the art will readily understand that the invention, having provided the polynucleotide sequences encoding *Chlamydia* polypeptides, also provides polynucleotides encoding

CLAIMS:

1. A nucleic acid molecule comprising a nucleic acid sequence which encodes a polypeptide selected from any one of:

(a) SEQ ID Nos: 12 to 16;

(b) an immunogenic fragment comprising at least 12 consecutive amino acids from a polypeptide of (a); and

(c) a polypeptide of (a) or (b) which has been modified without loss of immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

2. A nucleic acid molecule comprising a nucleic acid sequence selected from any one of:

(a) SEQ ID Nos: 3 to 10;

(b) a sequence which encodes a polypeptide encoded by any one of SEQ ID Nos: 3 to 10;

(c) a sequence comprising at least 38 consecutive nucleotides from any one of the nucleic acid sequences of (a) and (b); and

(d) a sequence which encodes a polypeptide which is at least 75% identical in amino acid sequence to any one of the polypeptides encoded by SEQ ID Nos: 3 to 10.

3. A nucleic acid molecule comprising a nucleic acid sequence which is anti-sense to the nucleic acid molecule of claim 1 or 2.

4. A nucleic acid molecule comprising a nucleic acid sequence which encodes a fusion protein, said fusion protein

comprising a first polypeptide and a second polypeptide, wherein the first polypeptide is selected from any one of:

(a) SEQ ID Nos: 11-16;

(b) an immunogenic fragment comprising at least 12 consecutive amino acids from a polypeptide of SEQ ID Nos: 11-16; and

(c) a polypeptide of (a) or (b) which has been modified without loss of immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

5. The nucleic acid molecule of claim 4 wherein the second polypeptide is a heterologous signal peptide.

6. The nucleic acid molecule of claim 4 wherein the second polypeptide has adjuvant activity.

7. A nucleic acid molecule according to any one of claims 1 to 6, operatively linked to one or more expression control sequences.

8. A vaccine comprising a vaccine vector and at least one first nucleic acid selected from any of:

(i) SEQ ID Nos: 1 to 10;

(ii) a nucleic acid sequence which encodes a polypeptide encoded by any one of SEQ ID Nos: 1 to 10;

(iii) a nucleic acid sequence comprising at least 38 consecutive nucleotides from any one of the nucleic acid sequences of (i) and (ii);

(iv) a nucleic acid sequence which encodes a polypeptide which is at least 75% identical in amino acid

sequence to the polypeptide encoded by any one of SEQ ID Nos: 1 to 10;

(v) a nucleic acid sequence which encodes a polypeptide whose sequence is set forth in any one of SEQ ID Nos: 11 to 16;

(vi) a nucleic acid sequence which encodes an immunogenic fragment comprising at least 12 consecutive amino acids from any one of SEQ ID Nos: 11 to 16; and

(vii) a nucleic acid sequence which encodes a polypeptide as defined in (i) to (v) or an immunogenic fragment as defined in (vi) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (i) to (v) or the corresponding fragment of (vi);

wherein each first nucleic acid is capable of being expressed and wherein the vaccine optionally comprises a second nucleic acid encoding and capable of expressing an additional polypeptide which enhances the immune response to the polypeptide expressed by the first nucleic acid.

9. A vaccine comprising a vaccine vector and at least one first nucleic acid encoding a fusion protein, wherein the fusion protein comprises:

(a) a first polypeptide selected from any of:

(i) a polypeptide encoded by any one of SEQ ID Nos: 1 to 10;

(ii) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from any one of SEQ ID Nos: 1 to 10;

(iii) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by any one of SEQ ID Nos: 1 to 10;

(iv) a polypeptide whose sequence is set forth in any one of SEQ ID Nos: 11 to 16;

(v) an immunogenic fragment comprising at least 12 consecutive amino acids from any one of SEQ ID Nos: 11 to 16; and

(vi) a polypeptide as defined in (i) to (iv) or an immunogenic fragment as defined in (v) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (i) to (iv) or the corresponding fragment of (v); and

(b) a second polypeptide;

wherein each first nucleic acid is capable of being expressed and wherein the vaccine optionally comprises a second nucleic acid encoding and capable of expressing an additional polypeptide which enhances the immune response to the first polypeptide.

10. The vaccine of claim 9 wherein the second polypeptide is a heterologous signal peptide.

11. The vaccine of claim 9 wherein the second polypeptide has adjuvant activity.

12. The vaccine of any one of claims 8 to 11 wherein wherein each first nucleic acid is operatively linked to one or more expression control sequences.

13. A vaccine comprising at least one first nucleic acid according to any one of claims 1, 2, and 4 to 7 and a vaccine

vector wherein each first nucleic acid is expressed as a polypeptide, the vaccine optionally comprising a second nucleic acid encoding an additional polypeptide which enhances the immune response to the polypeptide expressed by said first nucleic acid.

14. The vaccine of any one of claims 8 to 13 wherein the second nucleic acid encodes an additional *Chlamydia* polypeptide.

15. A pharmaceutical composition comprising a nucleic acid according to any one of claims 1 to 7 and a pharmaceutically acceptable carrier.

16. A pharmaceutical composition comprising a vaccine according to any one of claims 8 to 14 and a pharmaceutically acceptable carrier.

17. A unicellular host transformed with the nucleic acid molecule of claim 7.

18. An isolated nucleic acid probe of 5 to 100 nucleotides which hybridizes under stringent conditions to the nucleic acid molecule of any one of SEQ ID Nos: 3 to 10, or to a complementary or anti-sense sequence of said nucleic acid molecule.

19. An isolated primer of 10 to 40 nucleotides which hybridizes under stringent conditions to the nucleic acid molecules of any one of SEQ ID Nos: 3 to 10, or to a complementary or anti-sense sequence of said nucleic acid molecule.

20. A polypeptide encoded by a nucleic acid sequence according to any one of claims 1, 2 and 4 to 7.

21. A polypeptide comprising an amino acid sequence selected from any of:

(a) SEQ ID Nos: 12 to 16;

(b) an immunogenic fragment comprising at least 12 consecutive amino acids from a polypeptide of (a); and

(c) a polypeptide of (a) or (b) which has been modified without loss of immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

22. A fusion polypeptide comprising a first polypeptide and a second polypeptide, wherein the first polypeptide is selected from any one of:

(a) a polypeptide encoded by any one of SEQ ID Nos: 1 to 10;

(b) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from any one of SEQ ID Nos: 1 to 10;

(c) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by any one of SEQ ID Nos: 1 to 10;

(d) a polypeptide whose sequence is set forth in any one of SEQ ID Nos: 11 to 16;

(e) an immunogenic fragment comprising at least 12 consecutive amino acids from any one of SEQ ID Nos: 11 to 16; and

(f) a polypeptide as defined in (a) to (d) or an immunogenic fragment as defined in (e) which has been modified without loss of immunogenicity, wherein said modified

polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) to (d) or the corresponding fragment of (e).

23. The fusion protein of claim 22 wherein the second polypeptide is a heterologous signal peptide.

24. The fusion protein of claim 22 wherein the second polypeptide has adjuvant activity.

25. A method for producing a polypeptide of claim 20 or 21, or a fusion protein of any one of claims 22 to 24, comprising the step of culturing a unicellular host of claim 17.

26. An antibody against the polypeptide of claim 20 or 21, or against a fusion protein of any one of claims 22 to 24.

27. A vaccine comprising at least one first polypeptide selected from any of:

(i) a polypeptide encoded by any one of SEQ ID Nos: 1 to 10;

(ii) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from any one of SEQ ID Nos: 1 to 10;

(iii) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by any one of SEQ ID Nos: 1 to 10;

(iv) a polypeptide whose sequence is set forth in any one of SEQ ID Nos: 11 to 16;

(v) an immunogenic fragment comprising at least 12 consecutive amino acids from any one of SEQ ID Nos: 11 to 16; and

(vi) a polypeptide as defined in (i) to (iv) or an immunogenic fragment as defined in (v) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (i) to (iv) or the corresponding fragment of (v);

wherein the vaccine optionally comprises an additional polypeptide which enhances the immune response to the first polypeptide.

28. A vaccine comprising at least one fusion protein, wherein the fusion protein comprises:

(a) a first polypeptide selected from any of:

(i) a polypeptide encoded by SEQ ID No: 1;

(ii) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from SEQ ID No: 1;

(iii) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by SEQ ID No: 1;

(iv) a polypeptide whose sequence is set forth in SEQ ID No: 2;

(v) an immunogenic fragment comprising at least 12 consecutive amino acids from SEQ ID No:2; and

(vi) a polypeptide as defined in (i) to (iv) or an immunogenic fragment as defined in (v) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (i) to (iv) or the corresponding fragment of (v); and

(b) a second polypeptide;

wherein the vaccine optionally comprises an additional polypeptide which enhances the immune response to the first polypeptide.

29. The vaccine of claim 28 wherein the second polypeptide is a heterologous signal peptide.

30. The vaccine of claim 28 wherein the second polypeptide has adjuvant activity.

31. A vaccine comprising at least one first polypeptide according to any one of claims 20 to 24, optionally comprising an additional polypeptide which enhances the immune response to the first polypeptide.

32. The vaccine of any one of claims 27 to 31 wherein the additional polypeptide comprises a *Chlamydia* polypeptide.

33. A pharmaceutical composition comprising a polypeptide according to any one of claims 20 to 24 and a pharmaceutically acceptable carrier.

34. A pharmaceutical composition comprising a vaccine according to any one of claims 27 to 32 and a pharmaceutically acceptable carrier.

35. A pharmaceutical composition comprising an antibody according to claim 26 and a pharmaceutically acceptable carrier.

36. A method for preventing or treating *Chlamydia* infection using:

(a) the nucleic acid of any one of claims 1 to 7;

(b) the vaccine of any one of claims 8 to 14 and 27 to 32;

(c) the pharmaceutical composition of any one of claims 15, 16 and 33 to 35;

(d) the polypeptide of claim 20 or 21, or a fusion protein of any one of claims 22 to 24; or

(e) the antibody of claim 26.

37. A method of detecting *Chlamydia* infection comprising the step of assaying a body fluid of a mammal to be tested, with a component selected from any one of:

(a) the nucleic acid of any one of claims 1 to 7;

(b) the polypeptide of claim 20 or 21, or a fusion protein of any one of claims 22 to 24; and

(c) the antibody of claim 26.

38. A diagnostic kit comprising instructions for use and a component selected from any one of:

(a) the nucleic acid of any one of claims 1 to 7;

(b) the polypeptide of claim 20 or 21, or a fusion protein of any one of claims 22 to 24; and

(c) the antibody of claim 26.

39. A method for identifying a polypeptide of claim 20 or 21, or a fusion protein of any one of claims 22 to 24 which induces an immune response effective to prevent or lessen the severity of *Chlamydia* infection in a mammal previously immunized with polypeptide, comprising the steps of:

(a) immunizing a mouse with the polypeptide or fusion protein; and

(b) inoculating the immunized mouse with *Chlamydia*;

wherein the polypeptide or fusion protein which prevents or lessens the severity of *Chlamydia* infection in the immunized mouse compared to a non-immunized control mouse is identified.

ABSTRACT

The present invention provides purified and isolated polynucleotide molecules that encode *Chlamydia* polypeptides which can be used in methods to prevent, treat, and diagnose *Chlamydia* infection. In one form of the invention, the polynucleotide molecules are selected from DNA that encode polypeptides CPN100634 (SEQ ID Nos: 1, 2 and 11), CPN100635 (SEQ ID Nos: 3, 4, 12 and 13), CPN100638 (SEQ ID Nos: 5, 6 and 14), CPN100639 (SEQ ID Nos: 7, 8 and 15), CPN100708 (SEQ ID Nos: 9, 10 and 16).

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REPLY TO OTTAWA – FILE No.: 77813-2

March 6, 2001

BY COURIER

International Preliminary Examining
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Federal Republic of Germany

Dear Sirs:

Re: PCT Patent Application
Serial No. PCT/CA99/01147
Applicant: AVENTIS PASTEUR LIMITED
Inventor: Andrew D. Murdin, et al
Title: CHLAMYDIA ANTIGENS AND CORRESPONDING DNA FRAGMENTS AND USES THEREOF

– IPEA/ED-
PSH-

We request amendment of the specification pursuant to Article 34 (2b) of the Patent Cooperation Treaty. Please replace claim pages 50 to 55 containing 32 claims with the corresponding pages containing 39 claims, submitted herewith. Please also replace the abstract page with the enclosed replacement abstract page which has been renumbered.

A new set of claims has been submitted. Present claims 8 to 12 are new and correspond in subject matter to claim 8 as originally filed. Present claims 27 to 30 are new and correspond in subject matter to claim 22 as originally filed. Present claim 22 corresponds in subject matter to claim 17, as originally filed. The remaining claims have been renumbered. Correspondence between the new claims and the claims

which had been submitted with our response to the first Written Opinion of December 19, 2000 is as follows:

NEW CLAIMS	December 19, 2000 CLAIMS
1 to 7	1 to 7
8 to 12	New
13	8 and 9
14 to 26	10 to 22
27 to 30	New
31	23 and 24
32 to 39	25 to 32

The claim dependencies have been adjusted accordingly. The phrase "modified to improve its immunogenicity" has been replaced with "without loss of immunogenicity" throughout the claims. The main vaccine claims (present claims 8, 9, 27 and 28) have been converted to independent format. Present claim 22, directed to a fusion polypeptide, has also been converted from claim 17 as originally filed to independent claim format.

No new matter has been added. Entry of the amendments is respectfully requested.

Yours very truly,

SMART & BIGGAR

THN:ldg
Encl.

(Ms.) Thuy H. Nguyen

CLAIMS:

1. A nucleic acid molecule comprising a nucleic acid sequence which encodes a polypeptide selected from any one of:

(a) SEQ ID Nos: 12 to 16;

(b) an immunogenic fragment comprising at least 12 consecutive amino acids from a polypeptide of (a); and

(c) a polypeptide of (a) or (b) which has been modified without loss of immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

2. A nucleic acid molecule comprising a nucleic acid sequence selected from any one of:

(a) SEQ ID Nos: 3 to 10;

(b) a sequence which encodes a polypeptide encoded by any one of SEQ ID Nos: 3 to 10;

(c) a sequence comprising at least 38 consecutive nucleotides from any one of the nucleic acid sequences of (a) and (b); and

(d) a sequence which encodes a polypeptide which is at least 75% identical in amino acid sequence to any one of the polypeptides encoded by SEQ ID Nos: 3 to 10.

3. A nucleic acid molecule comprising a nucleic acid sequence which is anti-sense to the nucleic acid molecule of claim 1 or 2.

4. A nucleic acid molecule comprising a nucleic acid sequence which encodes a fusion protein, said fusion protein

comprising a first polypeptide and a second polypeptide, wherein the first polypeptide is selected from any one of:

(a) SEQ ID Nos: 11-16;

(b) an immunogenic fragment comprising at least 12 consecutive amino acids from a polypeptide of SEQ ID Nos: 11-16; and

(c) a polypeptide of (a) or (b) which has been modified without loss of immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

5. The nucleic acid molecule of claim 4 wherein the second polypeptide is a heterologous signal peptide.

6. The nucleic acid molecule of claim 4 wherein the second polypeptide has adjuvant activity.

7. A nucleic acid molecule according to any one of claims 1 to 6, operatively linked to one or more expression control sequences.

8. A vaccine comprising a vaccine vector and at least one first nucleic acid selected from any of:

(i) SEQ ID Nos: 1 to 10;

(ii) a nucleic acid sequence which encodes a polypeptide encoded by any one of SEQ ID Nos: 1 to 10;

(iii) a nucleic acid sequence comprising at least 38 consecutive nucleotides from any one of the nucleic acid sequences of (i) and (ii);

(iv) a nucleic acid sequence which encodes a polypeptide which is at least 75% identical in amino acid

sequence to the polypeptide encoded by any one of SEQ ID Nos: 1 to 10;

(v) a nucleic acid sequence which encodes a polypeptide whose sequence is set forth in any one of SEQ ID Nos: 11 to 16;

(vi) a nucleic acid sequence which encodes an immunogenic fragment comprising at least 12 consecutive amino acids from any one of SEQ ID Nos: 11 to 16; and

(vii) a nucleic acid sequence which encodes a polypeptide as defined in (i) to (v) or an immunogenic fragment as defined in (vi) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (i) to (v) or the corresponding fragment of (vi);

wherein each first nucleic acid is capable of being expressed and wherein the vaccine optionally comprises a second nucleic acid encoding and capable of expressing an additional polypeptide which enhances the immune response to the polypeptide expressed by the first nucleic acid.

9. A vaccine comprising a vaccine vector and at least one first nucleic acid encoding a fusion protein, wherein the fusion protein comprises:

(a) a first polypeptide selected from any of:

(i) a polypeptide encoded by any one of SEQ ID Nos: 1 to 10;

(ii) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from any one of SEQ ID Nos: 1 to 10;

(iii) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by any one of SEQ ID Nos: 1 to 10;

(iv) a polypeptide whose sequence is set forth in any one of SEQ ID Nos: 11 to 16;

(v) an immunogenic fragment comprising at least 12 consecutive amino acids from any one of SEQ ID Nos: 11 to 16; and

(vi) a polypeptide as defined in (i) to (iv) or an immunogenic fragment as defined in (v) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (i) to (iv) or the corresponding fragment of (v); and

(b) a second polypeptide;

wherein each first nucleic acid is capable of being expressed and wherein the vaccine optionally comprises a second nucleic acid encoding and capable of expressing an additional polypeptide which enhances the immune response to the first polypeptide.

10. The vaccine of claim 9 wherein the second polypeptide is a heterologous signal peptide.

11. The vaccine of claim 9 wherein the second polypeptide has adjuvant activity.

12. The vaccine of any one of claims 8 to 11 wherein wherein each first nucleic acid is operatively linked to one or more expression control sequences.

13. A vaccine comprising at least one first nucleic acid according to any one of claims 1, 2, and 4 to 7 and a vaccine

vector wherein each first nucleic acid is expressed as a polypeptide, the vaccine optionally comprising a second nucleic acid encoding an additional polypeptide which enhances the immune response to the polypeptide expressed by said first nucleic acid.

14. The vaccine of any one of claims 8 to 13 wherein the second nucleic acid encodes an additional *Chlamydia* polypeptide.

15. A pharmaceutical composition comprising a nucleic acid according to any one of claims 1 to 7 and a pharmaceutically acceptable carrier.

16. A pharmaceutical composition comprising a vaccine according to any one of claims 8 to 14 and a pharmaceutically acceptable carrier.

17. A unicellular host transformed with the nucleic acid molecule of claim 7.

18. An isolated nucleic acid probe of 5 to 100 nucleotides which hybridizes under stringent conditions to the nucleic acid molecule of any one of SEQ ID Nos: 3 to 10, or to a complementary or anti-sense sequence of said nucleic acid molecule.

19. An isolated primer of 10 to 40 nucleotides which hybridizes under stringent conditions to the nucleic acid molecules of any one of SEQ ID Nos: 3 to 10, or to a complementary or anti-sense sequence of said nucleic acid molecule.

20. A polypeptide encoded by a nucleic acid sequence according to any one of claims 1, 2 and 4 to 7.

21. A polypeptide comprising an amino acid sequence selected from any of:

(a) SEQ ID Nos: 12 to 16;

(b) an immunogenic fragment comprising at least 12 consecutive amino acids from a polypeptide of (a); and

(c) a polypeptide of (a) or (b) which has been modified without loss of immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

22. A fusion polypeptide comprising a first polypeptide and a second polypeptide, wherein the first polypeptide is selected from any one of:

(a) a polypeptide encoded by any one of SEQ ID Nos: 1 to 10;

(b) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from any one of SEQ ID Nos: 1 to 10;

(c) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by any one of SEQ ID Nos: 1 to 10;

(d) a polypeptide whose sequence is set forth in any one of SEQ ID Nos: 11 to 16;

(e) an immunogenic fragment comprising at least 12 consecutive amino acids from any one of SEQ ID Nos: 11 to 16; and

(f) a polypeptide as defined in (a) to (d) or an immunogenic fragment as defined in (e) which has been modified without loss of immunogenicity, wherein said modified

ABSTRACT

The present invention provides purified and isolated polynucleotide molecules that encode *Chlamydia* polypeptides which can be used in methods to prevent, treat, and diagnose *Chlamydia* infection. In one form of the invention, the polynucleotide molecules are selected from DNA that encode polypeptides CPN100634 (SEQ ID Nos: 1, 2 and 11), CPN100635 (SEQ ID Nos: 3, 4, 12 and 13), CPN100638 (SEQ ID Nos: 5, 6 and 14), CPN100639 (SEQ ID Nos: 7, 8 and 15), CPN100708 (SEQ ID Nos: 9, 10 and 16).

CLAIMS

1. A nucleic acid molecule comprising a nucleic acid sequence which encodes a polypeptide selected from any of:

(a) SEQ ID Nos: 11 to 16;

(b) an immunogenic fragment comprising at least 12 consecutive amino acids from a polypeptide of (a); and

(c) a polypeptide of (a) or (b) which has been modified to improve its immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

2. A nucleic acid molecule comprising a nucleic acid sequence selected from any of:

(a) SEQ ID Nos: 1 to 10;

(b) a sequence which encodes a polypeptide encoded by any one of SEQ ID Nos: 1 to 10;

(c) a sequence comprising at least 38 consecutive nucleotides from any one of the nucleic acid sequences of (a) and (b); and

(d) a sequence which encodes a polypeptide which is at least 75% identical in amino acid sequence to any one of the polypeptides encoded by SEQ ID Nos: 1 to 10.

3. A nucleic acid molecule comprising a nucleic acid sequence which is anti-sense to the nucleic acid molecule of claim 1 or 2.

4. A nucleic acid molecule comprising a nucleic acid sequence which encodes a fusion protein, said fusion protein comprising a polypeptide encoded by a nucleic acid molecule according to claim 1 and an additional polypeptide.

5. The nucleic acid molecule of claim 4 wherein the additional polypeptide is a heterologous signal peptide.

6. The nucleic acid molecule of claim 4 wherein the additional polypeptide has adjuvant activity.

7. A nucleic acid molecule according to any one of claims 1 to 6, operatively linked to one or more expression control sequences.

8. A vaccine comprising at least one first nucleic acid according to any one of claims 1, 2, and 4 to 7 and a vaccine vector wherein each first nucleic acid is expressed as a polypeptide, the vaccine optionally comprising a second nucleic acid encoding an additional polypeptide which enhances the immune response to the polypeptide expressed by said first nucleic acid.

9. The vaccine of claim 8 wherein the second nucleic acid encodes an additional *Chlamydia* polypeptide.

10. A pharmaceutical composition comprising a nucleic acid according to any one of claims 1 to 7 and a pharmaceutically acceptable carrier.

11. A pharmaceutical composition comprising a vaccine according to claim 8 or 9 and a pharmaceutically acceptable carrier.

12. A unicellular host transformed with the nucleic acid molecule of claim 7.

13. A nucleic acid probe of 5 to 100 nucleotides which hybridizes under stringent conditions to any one of nucleic acid molecules of SEQ ID Nos: 1 to 10, or to a homolog or complementary or anti-sense sequence of said nucleic acid molecule.

14. A primer of 10 to 40 nucleotides which hybridizes under stringent conditions to any one of nucleic acid molecules of SEQ ID Nos: 1 to 10, or to a homolog or complementary or anti-sense sequence of said nucleic acid molecule.

15. A polypeptide encoded by a nucleic acid sequence according to any one of claims 1, 2 and 4 to 7.

16. A polypeptide comprising an amino acid sequence selected from any of:

(a) SEQ ID Nos: 11 to 16;

(b) an immunogenic fragment comprising at least 12 consecutive amino acids from a polypeptide of (a); and

(c) a polypeptide of (a) or (b) which has been modified to improve its immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

17. A fusion polypeptide comprising a polypeptide of claim 15 or 16 and an additional polypeptide.

18. The fusion polypeptide of claim 17 wherein the additional polypeptide is a heterologous signal peptide.

19. The fusion protein of claim 17 wherein the additional polypeptide has adjuvant activity.

20. A method for producing a polypeptide of claim 15 or 16, comprising the step of culturing a unicellular host according to claim 12.

21. An antibody against the polypeptide of any one of claims 15 to 19.

22. A vaccine comprising at least one first polypeptide according to any one of claims 15 to 19 and a pharmaceutically acceptable carrier, optionally comprising a second polypeptide which enhances the immune response to the first polypeptide.

23. The vaccine of claim 22 wherein the second polypeptide comprises an additional *Chlamydia* polypeptide.

24. A pharmaceutical composition comprising a polypeptide according to any one of claims 15 to 19 and a pharmaceutically acceptable carrier.

25. A pharmaceutical composition comprising a vaccine according to claim 22 or 23 and a pharmaceutically acceptable carrier.

26. A pharmaceutical composition comprising an antibody according to claim 21 and a pharmaceutically acceptable carrier.

27. A method for preventing or treating *Chlamydia* infection using:

(a) the nucleic acid of any one of claims 1 to 7;

(b) the vaccine of any one of claims 8, 9, 22 and 23;

(c) the pharmaceutical composition of any one of claims 10, 11, 24 to 26;

(d) the polypeptide of any one of claims 15 to 19; or

(e) the antibody of claim 21.

28. A method of detecting *Chlamydia* infection comprising the step of assaying a body fluid of a mammal to be tested, with a component selected from any one of:

(a) the nucleic acid of any one of claims 1 to 7;

(b) the polypeptide of any one of claims 15 to 19; and

(c) the antibody of claim 21.

29. A diagnostic kit comprising instructions for use and a component selected from any one of:

(a) the nucleic acid of any one of claims 1 to 7;

(b) the polypeptide of any one of claims 15 to 19; and

(c) the antibody of claim 21.

30. A method for identifying a polypeptide of claims 15 to 19 which induces an immune response effective to prevent or lessen the severity of *Chlamydia* infection in a mammal previously immunized with polypeptide, comprising the steps of:

(a) immunizing a mouse with the polypeptide; and

(b) inoculating the immunized mouse with *Chlamydia;*

wherein the polypeptide which prevents or lessens the severity of *Chlamydia* infection in the immunized mouse compared to a non-immunized control mouse is identified.

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(54) Title: *CHLAMYDIA* ANTIGENS AND CORRESPONDING DNA FRAGMENTS AND USES THEREOF

(57) Abstract

The present invention provides purified and isolated polynucleotide molecules that encode *Chlamydia* polypeptides which can be used in methods to prevent, treat, and diagnose *Chlamydia* infection. In one form of the invention, the polynucleotide molecules are selected from DNA that encode polypeptides CPN100634 (SEQ ID Nos: 1, 2 and 11), CPN100635 (SEQ ID Nos: 3, 4, 12 and 13), CPN100638 (SEQ ID Nos: 5, 6 and 14), CPN100639 (SEQ ID Nos: 7, 8 and 15), CPN100708 (SEQ ID Nos: 9, 10 and 16).

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